



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/060,047	04/14/1998	RICHARD L. DUNN	8905.157US01	9184

7590 05/12/2005
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, PA
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/060,047	Applicant(s) DUNN, RICHARD L.	
	Examiner Edward J. Webman	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 14, 15, 19 and 29-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 14-15, 19, 29-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1617

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 14-15, 19, 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al.

Yamamoto et al teach a W/O emulsion composed of a water soluble drug containing solution as the inner aqueous phase and a polymer containing solution as the oil phase (abstract). Polylactic acid is disclosed (column 5 line 2). Ethyl acetate is specified (column 5 lines 58-59). Antiflammatory agents are disclosed (column 3 lines 21-22). A polymer concentration up to 80% is specified (column 6, lines 58-61). Starch is disclosed (column 4 line 41). The examiner takes Judicial notice under MPEP 2144.03 that starch is well-known in the art as an excipient. The examiner notes that in Yamamoto et al, the drug retaining substance is optional (column 4 lines 17-20).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 14, 15, 19, 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al.

Art Unit: 1617

Okada et al teach water-oil emulsions comprising a water-soluble drug in the aqueous phase and a polymer in the oil phase (abstract). Anti-inflammatory drugs are specified (column 1 line 45). Polylactic acid is disclosed (column 5, lines 1-5). A concentration of polymer up to 90% (w/w) is specified (column 5, lines 46-48). Ethyl acetate is disclosed (column 5 line 57). An intended use is not considered a patentable limitation during prosecution before the USPTO. Starch is disclosed as a drug retaining substance (column 4 lines 11-22, 33). The examiner takes notice under MPEP that starch is a well-known expedient, that is, an inert carrier for a drug. Applicant argues "consisting essentially of" overcomes the rejection. However he now claims an ^{P1}excipient in the aqueous medium.

The examiner cannot recall whether or not applicants' added limitation would not be considered an intended use. Assuming the former, applicants argue that both Yamamoto et al and Okada et al disclose further addition of their W/O emulsion into a W/O/W emulsion, which indicates that their W/O emulsions do not form the solid implant in an aqueous medium as now claimed. However, the conditions of addition and the volume of water taught in the prior art differ. For example, in Yamamoto et al, 4000 ml of the W/O emulsion are dispersed in 500 ml of an aqueous phase. Applicants' invention is intended to be supplied as a bolus in an unspecified volume of aqueous medium. It is argued that the prior art W/O emulsions will behave in the same manner under the same intended conditions as claimed because they are the same composition as claimed.

Art Unit: 1617


The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicants argue that the claimed mixture is cited in the abstract. However, the mixture is not recited in the specification.

The rejection is made non-final to afford applicants the opportunity to further elaborate why the now claimed limitation is not an intended use.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.

Webman/tgd

April 19, 2005


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500